

HEALTH AND SENIOR SERVICES

DIVISION OF HEALTH CARE QUALITY AND OVERSIGHT

Certificate of Need and Licensure: Regionalized Perinatal Services and Maternal
and Child Health Consortia

Proposed Amendments: N.J.A.C. 8:33C-1.2, 1.3, 1.4, 3.2 and 3.4

Authorized by: Marilyn Dahl, Deputy Commissioner,
Department of Health and Senior Services
(with the approval of the Health Care
Administration Board)

Authority: N.J.S.A. 26:2H-5 and 26:2H-8

Calendar Reference: See Summary below for explanation of
exception to calendar requirement.

Proposal Number: PRN 2004-282

Submit comments by October 1, 2004 to:

John A. Calabria, Director
Certificate of Need and
Acute Care Licensure Program
P.O. Box 360, Room 403
Trenton, New Jersey 08625

The agency proposal follows:

Summary

The Department of Health and Senior Services (Department) proposes amendments to N.J.A.C. 8:33C-1 and 3, in order to reflect amendments to N.J.S.A. 26:2H et seq., enacted as P.L.1998, c.43, that exempted hospitals providing Community Perinatal Center – Basic services, as well as all providers offering Community Perinatal Center – Birth Center services, from certificate of need requirements. Amendments are also proposed to reduce potential confusion as to the way in which these planning rules affect designated acute care children’s hospitals. The proposed amendments clarify that a children’s hospital is by definition a Regional Perinatal Center, including up to four intermediate care and six intensive care bassinets, and does not need to submit a separate certificate of need application for such designation and bassinets. In proposing these amendments, the Department is taking action consistent with its adoption in October, 2002 of N.J.A.C. 8:43G - 22A, Licensure of Children’s Hospital Designation. In both cases, the Department is responding to clinical and technological advances that have enabled sophisticated antepartum/fetal as well as postpartum/neonatal interventions at more optimal times in the development of the fetus or neonate. In view of these developments, it is essential to the health and

well-being of pregnant women and neonates in New Jersey that all designated Children's Hospitals be permitted to offer the most complex level of services to pregnant women and children, equivalent at a minimum to those found in a Regional Perinatal Center as well as a hospital authorized to provide pediatric intensive care.

The amendments to the rules are summarized below:

The proposed amendments to N.J.A.C. 8:33C-1.2 add a definition for a children's hospital, indicating that it is a general hospital which has received a designation as a children's hospital, either through legislation or receipt of a certificate of need from the Department. In addition, the definition of "Regional Perinatal Center" is modified to indicate that it includes any children's hospital.

N.J.A.C. 8:33C-1.3(a) is amended to indicate that Community Perinatal Center Intermediate and Intensive services as well as Regional Perinatal Center services shall not be initiated or expanded without a certificate of need. Additional proposed language states that a children's hospital is exempt from the general requirement not to initiate regional perinatal services, including up to four intermediate and six intensive

bassinets, without a certificate of need. Language is also added to clarify that, prior to licensure as a Regional Perinatal Center, a children's hospital shall document compliance with the requirements of N.J.A.C. 8:33C-3.4(a)3 through 10 as well as all applicable licensing requirements of N.J.A.C. 8:43G.

N.J.A.C. 8:33C-1.4(b)2 and 3 are amended to include new language exempting a children's hospital from the requirement to submit a certificate of need application in order to establish a Regional Perinatal Center.

N.J.A.C. 8:33C-1.4(c), requiring submission of a certificate of need application in order to establish a Community Perinatal Center – Basic or a Community Perinatal Center – Birth Center, is proposed for deletion. Subsequent subsections are recodified accordingly.

N.J.A.C. 8:33C-3.2(b) and (c) are deleted since Community Perinatal Center – Basic and Community Perinatal Center – Birth Center no longer require certificates of need.

N.J.A.C. 8:33C-3.4(d), (e) and (f), governing information to be provided in certificate of need applications by applicants seeking designation as a Community Perinatal Center Basic or Birth Center, as well as by children's hospitals, are proposed for deletion.

As the Department has provided a 60-day comment period for this notice of proposal, this notice is excepted from the rulemaking calendar requirements, pursuant to N.J.A.C. 1:30-3.3(a)5.

Social Impact

N.J.S.A. 26:2H-1 et seq., as amended, recognizes as "public policy of the State that hospitals and related health care services of the highest quality, of demonstrated need, efficiently provided and properly utilized at a reasonable cost are of vital concern to the public health."

Over the past decade there have been rapid changes in clinical practice and technology pertaining to perinatal and neonatal services. At the same time, as a result of P.L. 1998, c.43, providers of uncomplicated maternity services have been exempted from certificate of need requirements and the number of designated specialty acute care children's hospitals in New Jersey has been increased significantly. The public expects, and the Department agrees, that every designated children's hospital be capable of providing a highly sophisticated level of

care for children of all ages, including perinatal care for high risk pregnant women. The proposed amendments are consistent with the legislative action and public expectations in eliminating language incompatible with the current statutory requirements, as well as superfluous certificate of need process requirements.

Economic Impact

The costs to consumers and providers are not expected to change as a result of adopting the proposed amendments.

Federal Standards Statement

The proposed amendments do not impose standards on hospitals in New Jersey that exceed those contained in Federal law or regulation. Since there is currently no Federal regulation governing regional perinatal services, as described herein, a Federal standard analysis is not applicable to these proposed amendments.

Jobs Impact

Implementation of these proposed amendments provides clarification for standards previously in effect and implemented; therefore, this rulemaking is not expected to have an impact on jobs. There are currently a limited number of children's hospitals and all are designated as regional perinatal centers, so that this element of the proposed amendments should not result in the generation or loss of jobs. Likewise,

the 1998 statutory amendments exempting basic perinatal services from certificate of need requirements were implemented upon taking effect, and thus the proposed amendments should not result in the generation or loss of jobs.

Agriculture Industry Impact

The proposed amendments will not have any impact on the agriculture industry.

Regulatory Flexibility Statement

A Regulatory Flexibility analysis is not required because the proposed amendments do not impose reporting, recordkeeping or other compliance requirements on small businesses. The amendments proposed herein affect hospitals, which employ over 100 full-time employees. Thus, they are not defined as small businesses within the definition of that term, as set forth in N.J.S.A. 52:14B-15 et seq., and no Regulatory flexibility analysis is necessary.

Smart Growth Impact

The proposed amendments will not have an impact on the achievement of smart growth and the implementation of the State Development and Redevelopment Plan.

Full text of the proposal follows (additions indicated in boldface **thus**; deletions indicated in brackets [thus]):

SUBCHAPTER 1. GENERAL PROVISIONS

8:33C-1.2 Definitions

. . . The following words and terms, when used in this chapter, shall have the following meanings:

“Children’s hospital” means a general acute care hospital which has been designated as a children’s hospital either by statute or through receipt of an approved certificate of need from the Department.

. . .

“Regional Perinatal Center” means a general acute care hospital which is designated and licensed to provide care to high risk mothers and neonates, **and shall include any children’s hospital.** Such a facility provides consultation, referral, transport and follow-up care to other members of its Maternal and Child Health Consortium.

. . .

8:33C-1.3 Certificate of need

(a) In accordance with N.J.S.A. 26:2H-1 et seq., and amendments thereto, a MCHC or [perinatal] **Community Perinatal Center – Intermediate, Community Perinatal Center – Intensive, or Regional Perinatal Center** services shall not be instituted, constructed or expanded except upon application for, and receipt of, a certificate of need issued by the Commissioner in accordance with this chapter, N.J.A.C. 8:33 and N.J.S.A. 26:2H-1 et seq. **However, a children’s hospital, by virtue of its legislative designation or receipt of a certificate of need from the Department, is exempt from the requirement to apply for and receive a certificate of need to initiate the services associated with a Regional Perinatal Center, including up to four intermediate care bassinets and up to six intensive care bassinets. Prior to licensure, a children’s hospital shall document compliance with the requirements of N.J.A.C. 8:33C-3.4(a)3 through 10 as well as all applicable licensing requirements of N.J.A.C. 8:43G.**

(b) – (d) (No change.)

8:33C-1.4 Submission of certificate of need applications

(a) (No change.)

(b) No hospital shall engage in any of the activities specified in (b)1 through 4 below until it has submitted a certificate of need for full review pursuant to N.J.A.C. 8:33-4.1(a), and received approval thereof.

1. (No change.)

2. Establishment and designation of new services as a Regional Perinatal Center, Community Perinatal Center – Intensive and Community Perinatal Center – Intermediate, **except in the case of a Children’s Hospital as provided for in N.J.A.C. 8:33C-1.3(a);**

3. Changing its perinatal designation to Regional Perinatal Center, **except in the case of a children’s hospital as provided for in N.J.A.C. 8:33C-1.3(a),** Community Perinatal Center-Intensive and Community Perinatal Center Intermediate; or

4. (No change.)

(c) [A provider shall a submit certificate of need subject to expedited certificate of need review in accordance with N.J.A.C. 8:33-5.1 et seq. prior to:

1. Establishment and designation of new perinatal services as a Community Perinatal Center – Basic; or
2. Establishment and designation of new perinatal services as a Community Perinatal Center – Birth Center.]

Recodify existing (d) and (e) as **(c) and (d)** (No change in text.)

SUBCHAPTER 3. CERTIFICATE OF NEED REVIEW CRITERIA

8:33C-3.2 Facility certificate of need application review criteria

(a) (No change.)

[(b) Certificate of need applications submitted by an acute care hospital proposing to provide care to uncomplicated maternity and normal newborn patients, and requesting designation as a Community

Perinatal Center – Basic, shall be reviewed on the basis of the following:

1. That the hospital is in full compliance with the rules set forth at N.J.A.C. 8:33-5;
2. That the certificate of need applicant has become a general member or is a member in good standing of a MCHC;
3. Documentation that the certificate of need applicant has notified the appropriate MCHC of the services planned in accordance with the application; and
4. The certificate of need applicant 's intent and ability to assure access to patient care services as required through N.J.A.C. 8:33.

(c) Certificate of need applications submitted by a facility proposing to provide routine uncomplicated intrapartum care to pregnant women and/or their babies and requesting designation as a Community

Perinatal Center – Birth Center shall be reviewed on the basis of the following:

1. That the facility is in full compliance with the rules set forth at N.J.A.C. 8:33-5;
2. That the certificate of need applicant has become a general member or is a member in good standing of a MCHC;
3. Documentation that the certificate of need applicant has notified the appropriate MCHC of the services planned in accordance with the application; and
4. The certificate of need applicant's intent and ability to assure access to patient care services as required through N.J.A.C. 8:33.]

8:33C-3.4 Designation-specific certificate of need documentation

(a) – (c) (No change.)

[(d) In addition to the criteria at N.J.A.C. 8:33C-3.2(b), certificate of need applicants seeking designation as a Community Perinatal Center – Basic shall provide all of the following additional information in their certificate of need applications:

1. Documentation that the applicant shall provide care to patients expected to deliver neonates of a weight greater than 2,499 grams and at least 36 weeks gestational age;
2. Documentation that the application shall provide supportive care for infants returned from Regional or Community Perinatal Center – Intensive facilities;
3. That the hospital and the MCHC will enter into a letter of agreement stating that the hospital shall be a member of the MCHC for no less than five years. A draft copy of the letter of agreement shall be submitted with the certificate of need application; and
4. Letters of agreement valid for at least five years specific to coordination of services, transports and referrals shall

be developed and adopted between a Community Perinatal Center – Basic and a designated and licensed Community Perinatal Center – Intensive or Regional Perinatal Center. These letters of agreement shall be facilitated by the MCHC and comply with the regional transport system, as described in this chapter and N.J.A.C. 8:43G-19; and

5. Number of maternal-fetal and neonatal referrals and transports the applicant has made to a facility designated and licensed for advanced capabilities for the preceding two years and a projection of the needs for the next four years.

(e) In addition to the criteria specified at N.J.A.C. 8:33C-3.2(c), certificate of need applicants seeking designation as a Community Perinatal Center – Birth Center shall provide all of the following additional information in their certificate of need applications:

1. Documentation that the applicant shall provide care to patients expected to deliver neonates of a weight greater than 2,499 grams and at least 37 weeks gestational age and who require a stay of less than 24 hours after birth;
2. That the hospital and the MCHC will enter into a letter of agreement stating that the hospital shall be a member of the MCHC for no less than five years. A draft copy of the letter of agreement shall be submitted with the certificate of need application; and
3. Letters of agreement valid for at least five years specific to coordination of services, transports and referrals shall be developed and adopted between Community Perinatal Center – Birth Center and at a minimum, a designated and licensed Community Perinatal Center – Intermediate, located within 20 minutes transport time for medical care of a woman or an infant when complications arise during the antepartum, intrapartum, postpartum or newborn period.

(f) Designated specialty acute care children's hospitals, as specified in N.J.S.A. 26:2H-18a, 18c, 18d and 18e, shall provide highly specialized regional neonatal care. Certificate of need applicants must document in their certificate of need applications:

1. The ability to meet the criteria for the provision of neonatal services required of the Regional Perinatal Center including 24 hour a day, seven days a week, in-hospital coverage by a neonatologist, except that specialty acute care children's hospitals shall not be required to provide obstetric services; and
2. The capability of performing sub-specialty surgical procedures, and acting in a leadership role in providing the most recent technology in neonatal medicine and to the medical community throughout the State.】